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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,077	07/10/2003	Jose Luis Moctezuma de la Barrera	80015/043	3385

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,077

Applicant(s)

MOCTEZUMA DE LA BARRERA ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 12/12/2005 have been fully considered but they are not persuasive. Chader et al. provide disclosure of a surgical navigation system for providing accurate positional information of a surgical instrument relative to a patient and the ability to display diagnostic images with the positional information. The camera in the device of Adair provides positional information to the operator regarding the instrument and patient's anatomy and is therefore interpreted as a surgical navigation system. Adair teaches that commercially available displays allow attachment directly to a surgical instrument. One skilled in the art would recognize the value of the more accurate 3-D positional information provided by Chader et al. and of the safety implications of the "line of sight" offered by the instrument mounted display of Adair and be motivated to combine these elements in the interest of patient safety and operator ease of use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-17, 19,30 and 32-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,617,857 to Chader et al. in view of U.S. Patent 5,873,814 to Adair. Chader et al. teach an imaging system having a medical instrument including a source for emitting detectable energy and an instrument body having a work portion. The imaging system further includes a detector for detecting the energy and a processor for determining the location of the medical instrument

based on the detected energy (abstract). Chader et al. teach a need to correlate the position of a therapeutic or a surgical instrument during treatment with the produced diagnostic image of the treatment region so that the surgeon can correctly position the instrument at the treatment region (Col. 1, lines 25-32). The imaging system (Fig. 1, # 10) includes a medical instrument (12) that is connected to a processor. Also connected to the processor are a sensor assembly, a

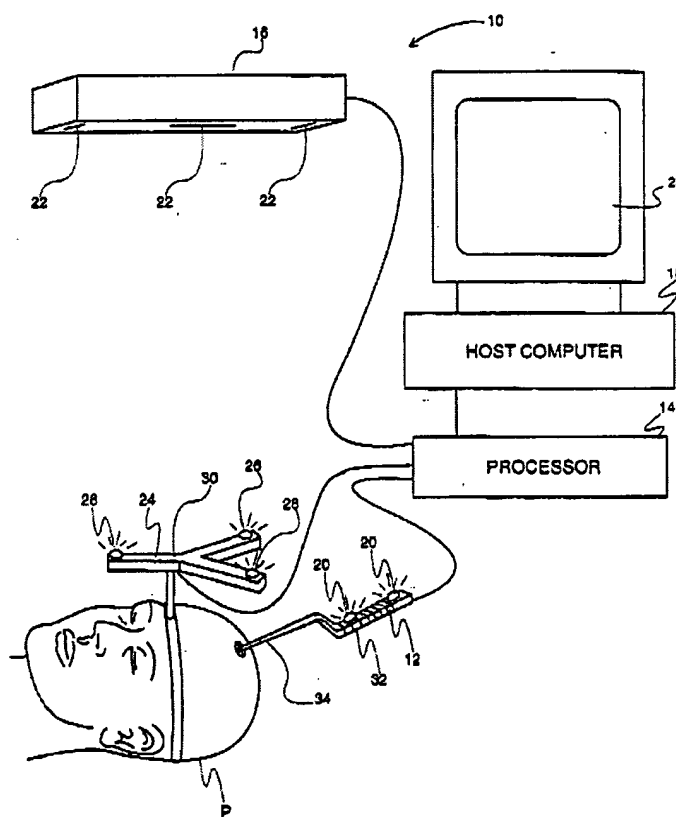


FIG. 1

host computer, and a reference frame. The medical instrument includes a plurality of energy-emitting elements for emitting energy that may be detected by sensors on the sensor assembly

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to determine the location of the energy-emitting elements in three-dimensional space thus forming a surgical navigation system. The reference frame is provided with a plurality of energy-emitting elements and is securely attached to a patient (P). Stored in the host computer, are previously obtained images of the patient, such as those obtained from an MRI scan. The location of the medical instrument may be tracked relative to the patient in real-time and correlated with the previously produced images of the patient's body which are displayed on a screen (28) of the host computer. To track the medical instrument in this manner, the medical instrument is advanced into the patient while the energy-emitting elements are energized and detected by the sensor assembly. The elements on the reference frame are also energized and detected so that the location of the medical instrument relative to the patient may be tracked by the processor, even when the patient is moved. The location information in the processor is then correlated with the previously produced images of the patient's body in the host computer so that as the surgeon moves the medical instrument to a treatment region, an image can be produced on the screen showing a position marker of the instrument relative to the previously produced images of the body. Chader et al. do not disclose the video monitor attached to the surgical instrument. Adair discloses the concept of a video display attached to a surgical instrument (Fig. 20), made feasible by a number of commercially available monitors. The display is located on the instrument so the operator does not have to "look away" from the work area during a procedure (Col. 15, lines 15-25). The display may be part of the instrument (Col. 12, line 44) or removable (Fig. 18). Function buttons may be provided on the display (Fig. 6, # 52). Adair discloses the communications link may be wireless (Col. 2, line 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the monitor with function buttons on the surgical instrument as taught by Adair in the invention of Chader et al. to provide the image in the operator's line of vision as suggested by Adair so

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the operator does not have to look away from the treatment site. Both Chader et al. and Adair are related to instrument positioning relative to a patient and therefore both related to surgical navigation. One skilled in the art would certainly look to related art in the development of improved systems.

Regarding claims 4, 17 and 30, with positional data from the sensors attached to the body and sensors attached to the instrument, data on the relative positioning (depth) is inherent.

Regarding claims 8-11, 24, 25 and 27 Chader et al. disclose an image can be produced on the screen showing a position marker of the instrument relative to the previously produced images (predetermined position) of the body. Such previous images are capable of displaying images of implants.

Regarding claim 12, the processor of Chader et al. provides the capability to display any set of data within the computer.

Regarding claims 13 and 26, the positional data of the instrument is interpreted as information provided by the instrument.

Regarding claims 14, 23 and 40, Adair teaches the use of wireless communication links.

Regarding claims 19 and 32, Adair teaches the display may be part of the instrument (Col. 12, line 44).

Regarding claims 35-39, 46-50 and 53-58, any surgical instrument requiring precision positioning would be obvious to use with the surgical navigation system and instrument mounted display.

Regarding claim 41, the method of use is clearly dictated by the structure. The display provides positional information of the instrument and the body being treated. The viewing of this information would be obvious, as would the step of completing the procedure using the display data.

Regarding claim 52, the real time positional display inherently provides kinematics information.

Claims 5, 18 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,617,857 to Chader et al. in view of U.S. Patent 5,873,814 to Adair and further in view of U.S. Patent Application Publication 2003/0078494 to Panescu et al. Adair and Chader et al. are discussed above, but do not disclose an LED display. Panescu et al. disclose an LED display with a medical instrument locating system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the LED display of Panescu et al. in the device of Adair/Chader et al. as such devices are well known and pervasive in the art for providing cost effective displays.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

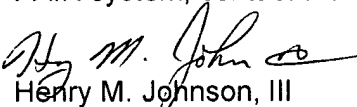
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

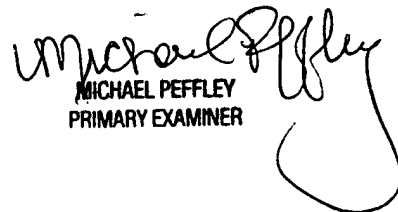
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Patent Examiner
Art Unit 3739


MICHAEL PEFFLEY
PRIMARY EXAMINER